



EUROPEAN
COMMISSION

Brussels, 9.7.2018
C(2018)4515 (final)

COMMISSION IMPLEMENTING DECISION

of 9.7.2018

withdrawing, at the holder's request, the marketing authorisation granted by Decision C(2004)3160 for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to the application submitted by Eli Lilly Nederland B.V. on 7 June 2018 with a view to the withdrawal of the marketing authorisation for the medicinal product "Ariclaim - duloxetine hydrochloride",

Whereas:

- (1) The placing on the market of the medicinal product "Ariclaim - duloxetine hydrochloride", which is entered in the Community register of medicinal products under the numbers EU/1/04/283 was authorised by Commission Decision C(2004)3160 of 11 August 2004.
- (2) Following the holder's request, that authorisation should be withdrawn,

HAS ADOPTED THIS DECISION:

Article 1

At the holder's request, the marketing authorisation granted by Decision C(2004)3160 of 11 August 2004 for the medicinal product "Ariclaim - duloxetine hydrochloride" is withdrawn.

Article 2

The withdrawal referred to in Article 1 shall be applicable with effect from 7 August 2018.

¹ OJ L 136, 30.4.2004, p. 1.

Article 3

This Decision is addressed to Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, Nederland.

Done at Brussels, 9.7.2018

For the Commission

Xavier PRATS MONNÉ

Director-General